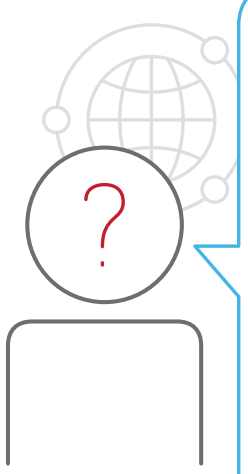
Improve data reliability and quality culture through UL's Data Integrity Program

Embed control into all GxP data management activities

The U.S. Food and Drug Administration (FDA), along with other global agencies, has recognized the quality and compliance risks caused by a lack of data integrity.

As noted by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-Operation Scheme (PIC/S) in the organization's August 2016 Data Integrity document, "Good data management practices influence the integrity of all data generated and recorded by a manufacturer, and these practices should ensure that data is accurate, complete and reliable."

Questions that quality assurance, clinical and operations executives are asking about data integrity:



- How can we build global awareness around data integrity within all facilities?
- How can we address data integrity gaps and share best practices within manufacturing, clinical, quality control laboratories (QC labs) and IT?
- How can we leverage technology and computer systems to improve data integrity through an operation that implements good practice regulations and quality guidelines (GxP)?
- How can we improve our quality culture so that GxP personnel are empowered to identify and correct any data integrity issues they encounter?

UL's Data Integrity program

UL's Data Integrity program includes a network of knowledgeable professionals to assess your organization's current data integrity practices, identify risks and make sustainable improvements.

The program empowers our customers to make changes to key procedures and processes that impact data integrity, including an evaluation of the technology used in their GxP environment.

We begin by working closely with customers to assess their current risks. We then provide educational programs and conduct mock audits to prepare the GxP workforce for regulatory inspections. Finally, we build sustainable program elements that help minimize risks of data integrity findings during audits.

Program elements

Our program helps companies identify and correct issues while building sustainable programs to reduce future risk of data integrity findings.

Orientation and awareness
The Data Integrity program begins with an electronic or on-site orientation through your organization, focused on core areas of GxP environments such as QC labs, batch record production and IT.

This initial education helps raise awareness about the importance of data integrity practices in the workforce. We will share best practices as they relate to understanding regulatory expectations, using technology and supporting a cultural transformation in minimizing risk of data integrity findings.

Data integrity gaps/risk assessment
We conduct interviews with key leaders and stakeholders within a customer's organization to better understand the organization's culture and, through the production life cycle, the challenges that arise from it as it relates to data integrity, baseline processes, tools and methodologies and how technology is used to enable processes.

Our team assesses an organization's policies, procedures and practices against regulatory guidance for data integrity and industry best practices. We also conduct audits of high-risk areas/functions/facilities identified during our assessment. We then review our findings and observations with key stakeholders and establish a plan to address — and resolve — gaps and risks.

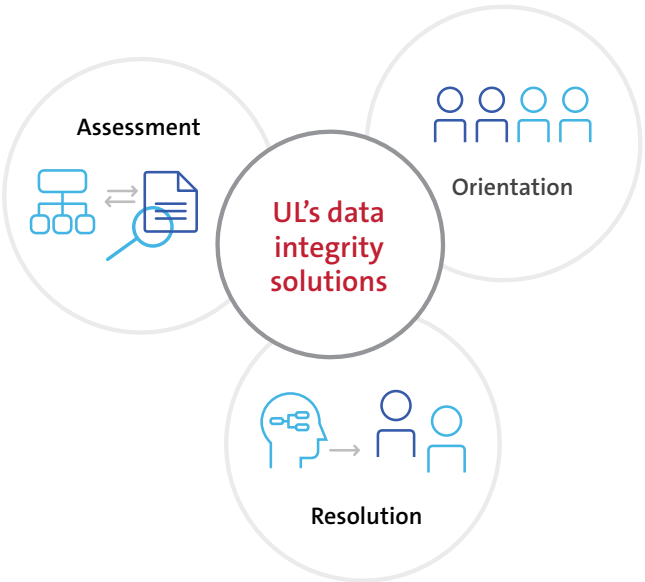
Audit resolution
Once gaps and risks related to data integrity have been identified, we work closely with the customer's team to recommend and support issue resolution.

An ongoing problem

According to the U.S. FDA Center for Drug Evaluation and Research (CDER) Office of Compliance (OC), 21 out of the 28 warning letters recorded during a recent 15-month period included data integrity observations.

A second audit of high-risk areas may also be conducted to confirm that recommended changes were made and best practices and procedures for a high-quality/data integrity process, culture and practices are embedded within the organization. We also offer coaching to help customers prepare for an agency inspection and minimize the risks of data integrity observations.

The process of ongoing regulatory updates and mock audits can be supported on a long-term basis, helping confirm ongoing/anytime compliance and quality and improved productivity with a more engaged workforce.



Improve data management and quality culture within GxP areas

Contact UL today to learn how our data integrity solutions help minimize regulatory risks and improve quality across your organization.

ComplianceWire®

ComplianceWire® learning management system (LMS) was designed specifically for highly regulated industries. This web-based platform effectively and efficiently automates the creation, delivery and reporting of your role-based trainings, qualifications and compliance programs.

Our time-tested technology is used extensively by U.S. and global pharmaceutical, medical device and biologics companies as well as global regulatory authorities in the U.S., China and India.

UL, the global safety science leader, delivers testing, inspection and certification (TIC), training and advisory services, risk management solutions and essential business insights to help our customers — based in more than 100 countries — achieve their safety, security and sustainability goals. Our extensive knowledge of products and intelligence across supply chains makes us the partner of choice for customers with complex challenges.

To learn more about how to achieve enterprisewide compliance, quality and performance goals with ComplianceWire® LMS, visit UL.com or call +1.609.627.5300 to speak with one of our LMS product specialists.

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